

THE SIGNIFICANT ROLE OF LEGAL REGULATIONS AND STANDARDISATION IN THE DEVELOPMENT OF TELEMEDICINE IN THE EU

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Abstract

Purpose – The main aim of this article is to analyze and evaluate EU policies and legislation concerning telemedicine. Therefore, the article aims to identify the legal instruments which could be implemented to guarantee the development of telemedicine among the Member States of the EU, which will take place with respect to patient welfare and interoperability of healthcare systems.

Design/methodology/approach – **As for its methodology**, this research focuses on the EU policies, legislation and a few recent initiatives that were undertaken by Poland and other EU Member States in the area of telemedicine. This research utilizes qualitative research methods. The textual analysis method has been used to examine the content and meaning of legal texts and other documents as well as their structure.

Findings – The phenomenon of telemedicine is an extremely complex issue. This implies that the attempt to provide health services based on such solutions requires a comprehensive approach, taking into account not only the normative material related to the healthcare but also a number of sectoral regulations relating to, for example, personal data protection and cybersecurity rules, patients' rights, or to the provisions governing electronic commerce. On the other hand, most regulations concerning directly telemedicine occur in the area of *soft law*. Due to this fact, there are significant differences in national regulations. Therefore, institutions involved in the EU legislation should focus on implementing general standards in telemedicine, which would guarantee patient welfare. Finally, the significant challenge is to provide interoperability between telemedicine solutions available around the European Union. This is a *sine qua non* condition for a greater utilization of telemedicine solutions by EU citizens.

Research limitations/implications – The scope of the research covers the examination of the EU policies and legislation on telemedicine. This article does not cover wide and complex research on sectoral regulations relating to, for example, personal data protection and cybersecurity rules, patient rights, or finally to the provisions governing electronic commerce. It covers the comparative analysis of telemedicine in Poland and only general analyses concerning different countries, e.g. France or the USA.

Practical implications – The findings may give some reference to institutions involved in the EU legislation, especially to the European Commission. Therefore, they can be useful for improving the Member States' legal frameworks on telemedicine.

Originality/Value – Contrary to the majority of papers on telemedicine, this article does not concentrate on the barriers and challenges for the successful implementation of telemedicine but focuses on solutions. What is more, this research covers the latest regulations and publications. Finally, the article presents the current Polish legislation promoting telemedicine solutions, which may prove an interesting case study for researchers from different countries.

Keywords: telemedicine, telehealth, teleconsultations, healthcare, eHealth, interoperability

Research type: research paper.

Introduction

The development of Information and Communication Technologies (ICT) has created hitherto unknown possibilities of providing health services at a distance. The above trend led to the formulation of the term "telemedicine". According to the definition proposed by the European Commission, "telemedicine is the provision of healthcare services, through use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients"¹.

The potential of telemedicine technologies is indisputable: it can provide new cost-effective and efficient methods of delivering healthcare as well as improve health and quality of life of thousands of patients (PWC, 2018). Furthermore, numerous studies have already demonstrated improved clinical outcomes through the use of telemedicine applications (Khan and Driessen, 2018). Taking into account the dynamic development of new technologies as well as the growing demand for medical services - which results even from the aging of the population - it seems inevitable that telemedicine solutions will expand in current treatment activities. This tends to confirm the results of last research: the number of mHealth apps available in the market has increased substantially. In 2017 there was over 318,000 health apps available on the top app stores worldwide, nearly double the number of apps available in 2015 - with more than 200 apps being added each day (IQVIA, 2017). It is therefore not surprising that the authors of the report on Global Markets for Telemedicine Technologies anticipate the rapid development of telemedicine. As a comparison, in 2018 the global telemedicine market totalled \$31.2 billion and is estimated to reach \$72.5 billion by 2023, growing at a compound annual growth rate (CAGR) of 18.3% for the period between 2018 and 2023 (BCC Research, 2018).

On the other hand, the contemporary development of telemedicine among the Member States of the European Union leaves a lot to be desired. Although the concept of telemedicine has been present in EU policies and strategies for over 15 years, the total EU market share of these services still remains marginal. According to a survey requested by the European Commission, in the last 12 months before March 2017, less than one in five respondents have used health and care services provided online (18%), 5% have used these "once", 6% "twice" and 7% "three times or more". The majority (81%) have "never" used these services" (TNS Political & Social, 2017²). One indication of this symptom is the European Parliament Resolution of 12 February 2019 on the Implementation of the Cross-Border Healthcare Directive. In this Resolution, the European Parliament pointed out that "the application of the directive with regard to telemedicine - health services provided remotely - has led to a certain lack of clarity concerning reimbursement schemes, as some Member States do reimburse or provide consultation with general or specialised practitioners at a distance, while others do not"³. In this respect, the European Parliament calls upon the European

¹ Communication of 4 November 2008 from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society. COM (2008) 0689 final.

² This survey was carried out by TNS Political & Social network in the 28 Member States of the European Union between 18th and 27th of March 2017. Some 27,901 EU citizens from different social and demographic categories were interviewed face-to-face at home and in their native language on behalf of the Directorate-General for Communications Networks, Content and Technology.

³ European Parliament Resolution of 12 February 2019 on the Implementation of the Cross-Border Healthcare Directive. 2018/2108 (INI).

Commission to “support the uptake of the reimbursement rules, in accordance with Articles 7(1) and 4(1), so that they also apply to telemedicine, where appropriate”. Moreover, the European Parliament pointed out that the European Commission should “encourage the Member States to align their approaches to the reimbursement of telemedicine”¹.

Furthermore, ensuring that patients have access to the convenience and benefits afforded by telemedicine technologies is not enough. Telemedicine malpractice cases are likely to increase the more widely it is used. Thus, there is a question of the legislative strategy: do we need a law for regulating the use of telemedicine technologies in the practice of medicine to guarantee the appropriate standards of care in the delivery of medical services directly to patients via telemedicine technologies? Or maybe the better solution is to depend on liberalisation and the free market.

In light of these considerations, the question arises of what the EU legislation is concerning telemedicine. Therefore, the article aims to identify the legal instruments which could be enforced to remove barriers to widespread appropriate adoption of telemedicine technologies for delivering care while ensuring the public health, patient welfare and safety.

Definition and genesis of telemedicine

On the basis of the EU legal system, there is currently no legal definition of the concept of telemedicine. Moreover, in many documents of the international organizations, as well as in the literature, there is a noticeable terminological chaos concerning this issue. This is evidenced on the one hand by a multitude of concepts related to the aspects of modern healthcare under development in recent years (e.g. telemedicine, telehealth, telecare, eHealth, mHealth, cybermedicine), and on the other hand, no consistency in their application (Mazurkiewicz and Klach, 2017; Botrugno C. 2018).

The lack of a unified nomenclature is present also in the legislation of the United States of America. According to the research of the Center for Connected Health Policy (CCHP), the states alternate between using the term “telemedicine” or “telehealth”. In some states, both terms are explicitly defined in law and/or policy and regulations. “Telehealth” is sometimes used to reflect a broader definition, while “telemedicine” is used mainly to define the delivery of clinical services (CCHP, 2018). In addition, the authors of a Market study on telemedicine suggest

that “telehealth is a more generic term that refers to health-related procedures, while telemedicine refers more specifically to treating people from distance” (PWC, 2018). On the other hand, they pointed out that “eHealth and mHealth are terms that are as generic as telehealth in terms of health services, but specific to the technologies used in delivering these services from distance: the Internet and mobile devices respectively” (PWC, 2018).

Given the above, a lot of researchers describe “telemedicine” as “providing medical care at a distance”². This definition derives from a combination of a prefix “tele”, (from Ancient Greek *τῆλε* [*têle*], “at a distance”), which is a typical part of compound words that indicate their semantic connection with distance actions (e.g. telephone, teleoperator, telemarketer)

¹ *Ibidem*.

² See: Volkert S. E. 2000. Telemedicine: Rx for the Future of Health Care. *Michigan Telecommunications and Technology Law Review*, Vol. 6. 147 (2000). For more definitions see: Darkins A. W., Cary M. A. 2000. *Telemedicine and Telehealth: Principles, Policies, Performances and Pitfalls*. New York: Springer Company Publishing Inc. pp. 1-24; Maheu M.M., Whitten P., Allen A., *E-Health, Telehealth, and Telemedicine: A Guide to Startup and Success*, San Francisco 2001, pp. 2-4.

and a Latin term “*medicina*”¹. As a result, the term telemedicine is defined as “healing from a distance”.

It should be noted that Dr. K. Bird may be considered to be the author of the term “telemedicine” (Murphy and Bird). During his research in the 1960s he started to use the term telemedicine. What is more, in their papers published in 1974, Bird and Murphy described the tediagnosis as “system which utilizes diagnostic instrumentation to reproduce closely the normal clinical setting wherein patient and doctor are in the same room”. What is interesting, the first example of using technology to deliver medical care from a distance was implemented in the early 1900s by a Dutch physiologist - Dr. Willem Einthoven. In 1903 W. Einthoven mastered the art of recording electrocardiogram among patients in a hospital located 1 km from the place where he read the results. This was done using a string galvanometer (the so-called Einthoven galvanometer) and telephone lines. As a result, W. Enithoven is considered to be the founder of the first electrocardiography, as well as the first scientist-clinician, who on a relatively large scale applied technology of a similar purpose to that used for the needs of modern telemedicine utilizing a string galvanometer that he designed and was the birth of clinical electrocardiography (Stowe and Harding, 2010). By the 1960s, technology progressed to represent the modern form of telemedicine. Military and space industries were the first to create and adopt the technology required to deliver this modern care (WHO, 2010).

The advancements and continued development of medical and communications technology have had a profound impact on present understanding of telemedicine. As a result, the simplest definition of telemedicine (providing medical care at a distance) seems to be a too far-reaching simplification. Therefore, the common idea is to limit the definition of telemedicine by requiring utilisation of ICT. As Maurice and Caron rightly pointed out the “use of ICT or telecommunications to the definition of telemedicine limits the scope of activities but incorporates ICT-based activities that are not necessarily considered to be ‘telemedicine’”. As an example, these authors quote the use of ‘telephone’ in clinical practice, which was reported in the *Lancet* in 1879. Despite its slow uptake and early resistance from conservative physicians, the telephone is now an integral part of medicine, for communication with colleagues and patients, at a distance, to facilitate healthcare (Maurice and Caron, 2010). Because of that, the Federation of State Medical Boards (FSMB)² in the Model policy for the appropriate use of telemedicine technologies in the practice of medicine, stated that “generally, telemedicine is not an audio-only, telephone conversation, e-mail/instant messaging conversation, or fax”. Regardless of this policy, telemedicine “means the practice of medicine using electronic communications, information technology or other means between a licensee in one location, and a patient in another location with or without an intervening healthcare provider (...). It typically involves the application of secure videoconferencing or store and forward technology to provide or support healthcare delivery by replicating the interaction of a traditional encounter in person between a provider and a patient” (FSMB, 2014).

¹ Wiktionary, the free dictionary. “Tele-“, [interactive]. [accessed 2019-05-04]. <<https://en.wiktionary.org/wiki/tele->>.

² The Federation of State Medical Boards represents the 70 state medical and osteopathic regulatory boards—commonly referred to as state medical boards—within the United States, its territories and the District of Columbia. It supports its member boards as they fulfill their mandate of protecting the public health, safety and welfare through the proper licensing, disciplining, and regulation of physicians and, in most jurisdictions, other healthcare professionals. See: The Federation of State Medical Boards official website: <<https://www.fsmb.org/about-fsmb/>>.

An important point of reference in defining the concept of telemedicine is the acquis of the World Health Organization. For example, in its famous Report the WHO explains that telemedicine is “the delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities” (WHO, 1998).

Another crucial definition, especially among the EU Member States, was proposed in Communication of 4 November 2008 from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society (further also: “Communication COM (2008) 689”). As mentioned before, in this document the European Commission described telemedicine as “the provision of healthcare services, through use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location”. According to Communication COM (2008) 689 “it involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients”. In the further part of the Communication, the Commission states that telemedicine encompasses a wide variety of services. Those most often mentioned in peer-reviews are “teleradiology, telepathology, teledermatology, teleconsultation, telemonitoring, telesurgery and teleophthalmology”. Other potential services include call centers/online information centers for patients, remote consultation/e-visits or videoconferences between health professionals. It is worth noting that the European Commission excludes from the telemedicine services catalogue “health information portals, electronic health record systems, electronic transmission of prescriptions or referrals (e-prescription, e-referrals)”.

In conclusion, the definition of telemedicine, in spite of what may appear, is not just an object of an academic dispute. The legal understanding of telemedicine may be crucial both - in medical and legal practice. The regulation in this area may alter the scope of practice or authorize the delivery of remote healthcare services. Such decisions may be also crucial for a number of physicians and other medical professionals, as well as producers of medical devices. In consequence, the institutions involved in the EU legislation should take into consideration what is the expected model of telemedicine among the Member States. This discussion should deliver a proposition of telemedicine definition. Without the precise scope of activities which are classified as telemedicine practice, there will be a wide range of systems among the 28 old EU countries. As a result, the telemedicine systems would be just local, limited to a maximum one or several states. Furthermore, it will be very difficult or even impossible to guarantee the interoperability of the telemedicine system around the EU Member States.

Telemedicine in the light of EU policies and regulations

Although telemedicine has not yet been legally defined under EU law, this concept has been present in the area of EU *soft law* acts for over 15 years¹. Namely, for the first time it

¹ Some authors, among the initiatives that increase the use of telemedicine in Europe, present also older European acts. For example, Vera Lúcia Raposo cataloged among them Decision No 276/1999/EC of the European Parliament and of the Council of 25 January 1999 adopting a multiannual Community action plan on promoting safer use of the Internet by combating illegal and harmful content on global networks (OJ L 33, 6.2.1999, pp. 1–11) and Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions - eEurope 2002: Quality Criteria for Health

appeared in Communication of 30 April 2004 from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions e-Health - making healthcare better for European citizens: an action plan for a European e-Health Area¹. In the Communication cited, the European Commission clearly exposes the potential of telemedicine services as one of the key areas of eHealth. Interestingly, already in 2004 the European Commission noticed the possibility of implementing telemedicine systems, and within them, such services as, tele-consultations (second medical opinion), telemonitoring and telecare, either in the home or the hospital.

One of the first documents referring directly to the issue of telemedicine was the European Parliament Resolution of 23 May 2007 on the impact and consequences of the exclusion of health services from the Directive on services in the internal market². In the above-mentioned Resolution, the European Parliament invites the Commission to encourage the Member States to actively support the introduction of e-health and telemedicine. In addition, the European Parliament pointed out that “telemedicine and e-health are developing on such a scale that new rules of play need to be agreed in the areas of social protection, funding and access to such care”. Finally, the European Parliament “calls on the Commission to draw up technical standards, and calls on the governments of the Member States to actively support the introduction of interoperable transparent information systems allowing effective exchange and sharing of information on health between health care providers in different Member States”.

Although, since 2004, telemedicine has been more and more clearly marking its place in the EU health policy, it has not been particularly highlighted in the Commission White Paper of 23 October 2007 entitled “Together for Health: A Strategic Approach for the EU 2008-2013”³. Nevertheless, the document recognizes the impact on healthcare systems of the rapid development of new technologies, including information and communication technologies (so-called ICT).

There is no doubt that the milestone for the development of telemedicine in the EU was the previously cited Communication of 4 November 2008 from the Commission on telemedicine for the benefit of patients, healthcare systems and society. The purpose of this Communication was, on the one hand, to identify the main obstacles to a wider use of telemedicine, and to identify ways to overcome them. Therefore, Communication COM (2008) 689 expressly indicated that the aim of this Communication is to support the Members States in achieving a large-scale and beneficial deployment of telemedicine services, by focusing on three strategic sets of actions:

- 1) building confidence in and acceptance of telemedicine services
- 2) bringing legal clarity
- 3) solving technical issues and facilitating market development.

Importantly, the European Commission has not only indicated the general direction of activities in the field of telemedicine, but also identified specific actions to achieve them.

related Websites (COM (2002) 0667 final). Nevertheless, the above documents do not refer directly to telemedicine. See: Raposo V. L. 2016. The legal framework (or the lack of it) in Europe, *GMS Health Technology Assessment*. Vol. 12. pp. 1-12.

¹ Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions e-Health - making healthcare better for European citizens: an action plan for a European e-Health Area. COM (2004) 0356 final.

² OJ E 102, 24.04.2008 P. 0279 – 0286.

³ COM (2007) 630 final.

Among them, there were soft activities¹, pilot and implementation activities², activities supporting the exchange of experiences and good practices³ and – last but not least - standardisation activities⁴. In addition, the Commission called on Member States to carry out:

1) by the end of 2009, the assessment of their needs and priorities in telemedicine, indicating that these priorities should be part of the national health strategies;

2) by the end of 2011, the assessment and adoption of their national regulations enabling wider access to telemedicine services.

The direction of action indicated by the Commission was favourably received by the European Economic and Social Committee⁵ and was then included in other *soft law* level papers at the EU level and in principle is still a key reference point in the telemedicine discussion. Nevertheless, it seems that Communication (2008) 689 did not bring the expected results in such a short time as the European Commission expected. As an example, in Poland the first system regulations regarding telemedicine entered into force on 12 December 2015⁶. The above delays may arise from the fact that Communication COM (2008) 689 - being solely a soft law source - does not give the European Commission real legal instruments to enforce its assumptions.

Another important document from the point of view of the development of telemedicine was - *nota bene* currently implemented - Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century (COM/2012/0736 final)⁷. The unambiguous depiction of telemedicine in the second eHealth Action Plan confirmed the priority of this element in the EU health policy. In addition, this document showed numerous opportunities related to the development of the telemedicine market. The important position of telemedicine in the EU health policy was further confirmed in the Green Paper of 10 April 2014 on mobile health ('mHealth')⁸. In this document, the European Commission indicated that mHealth "includes applications (...) such as lifestyle and wellbeing apps that may connect to medical devices or sensors (e.g. bracelets

¹ For example, the Commission decided to support the development, by 2011, of guidelines for consistent assessment of the impact of telemedicine services, including effectiveness and cost effectiveness. This was based on the work of experts in the field, the Commission supported studies, large-scale pilot schemes and relevant research projects.

² For example, the Commission decided to support via its Competitiveness and Innovation Programme a large-scale telemonitoring pilot project. This included a network of procurers and payers of healthcare services.

³ For example, the Commission proposed to contribute to European collaboration between health professionals and patients in key areas with the potential for a greater application of telemedicine, in order to make specific recommendations on how to improve confidence in and acceptance of telemedicine, also taking into account ethical and privacy related aspects.

⁴ By the end of 2011, in cooperation with Member States, the Commission decided to issue a policy strategy paper on how to ensure interoperability, quality and security of telemonitoring systems based on existing or emerging standards at the European level.

⁵ See: Opinion of the European Economic and Social Committee on the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society (COM(2008) 689 final). 2009/C 317/15. OJ C 317, 23.12.2009, pp. 84–88.

⁶ See: Act of October 2015, 9 amending the Act on the information system in health care and certain other laws; Journal of Laws of 2015, item 1991. Original title: ustawa z dnia 9 października 2015 r. o zmianie ustawy o systemie informacji w ochronie zdrowia oraz niektórych innych ustaw.

⁷ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century. COM (2012) 0736 final.

⁸ Green Paper on mobile Health ("mHealth"). COM (2014) 0219 final.

or watches) as well as personal guidance systems, health information and medication reminders provided by sms and telemedicine provided wirelessly”.

In the debate on the development of telemedicine, one cannot overlook the EU acquis in the area of the EU digital policy. In fact, telemedicine has got a dualistic character: it regards not only the healthcare regulations but also the whole package of legislation concerning digital and telecommunication aspects. For example, in Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions EU titled eGovernment Action Plan 2016-2020 - Accelerating the digital transformation of government, the Commission has declared that it is going to “support Member States in the development of eHealth services that also enable cross-border exchange of e-prescriptions, based on the e-prescription guidelines adopted by the eHealth Network and telemedicine and tele-monitoring solutions, in particular for the successful provision of treatment by the European Reference Networks”¹

However, one of the latest EU documents relating to the issue of e-Health, and indirectly also to telemedicine, was the Communication of the European Commission of 25 April 2018 on enabling the digital transformation of health and care in the Digital Single Market - empowering citizens and building a healthier society². The European Commission pointed out from the very beginning that “health and care systems require reforms and innovative solutions to become more resilient, accessible and effective in providing quality care to European citizens”. At the same time, the Commission recognizes that digital solutions in the field of health and social care can contribute to the well-being of millions of citizens and radically change the way healthcare and social services are delivered to patients, provided that they are deliberately designed and implemented in a cost-effective manner. In connection with the above, a number of activities are planned by the European Commission in the near future. However, from the point of view of the development of a telemedicine concept, the following are crucial:

1) support cooperation to stimulate the supply and uptake of digital health by promoting common principles for validating and certifying health technology;

2) support the exchange of innovative and best practices, capacity building and technical assistance for health and care authorities (for using open standards and interoperable digital solutions to promote health, prevent and manage chronic conditions, empower people and centre care on the person), with financial support from Horizon 2020, the Structural Reform Support Programme 57 and the third "Health" programme, within the current budgets, while considering making proposals for further support under the next multi-annual financial framework;

3) promote knowledge and skills of citizens, patients and health and care professionals in using digital solutions in collaboration with health professional organisations and academia.

What is important, the above-mentioned plans correspond to the general ideas which were presented in Communication from the Commission entitled “A Digital Single Market Strategy for Europe” in which it was stressed that “the Commission will launch an integrated standardisation plan to identify and define key priorities for standardisation with a focus on the technologies and domains that are deemed to be critical to the Digital Single Market,

¹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions EU titled eGovernment Action Plan 2016-2020 - Accelerating the digital transformation of government. COM (2016) 0179 final.

² Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society. COM (2018) 233 final.

including essential sectoral interoperability and standards in areas such as health (telemedicine, m-health), transport (travel planning, e-freight), environment, and energy”¹.

To sum up, it should be pointed out that telemedicine has been present in the EU policies for more than 15 years. Nevertheless, telemedicine is only an element of the main EU policies (e.g. eHealth and digital policies). Therefore, it seems that the further development of telemedicine among the EU countries requires a dedicated strategy or policy for the development of such solutions in healthcare.

Telemedicine in the light of Directive 2011/24/EU (patients' rights in cross-border healthcare)

It should be pointed out that there are also hard law regulations directly relating to telemedicine. However, currently it is only Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare². The above EU normative act refers to telemedicine in Art. 3 (d) and Art. 7 para. 7 of Directive 2011/24/EU. In accordance with Article 3 (d), 'Member State of treatment' means "the Member State on whose territory healthcare is actually provided to the patient. In the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established". In addition, Art. 7 of Directive 2011/24/EU also deserves to be noted because it sets out the general rules for the reimbursement of costs incurred by the insured benefitting from cross-border healthcare. In the light of the above-mentioned Article,

"the Member State of affiliation may impose on an insured person seeking reimbursement of the costs of cross-border healthcare, including healthcare received through means of telemedicine, the same conditions, criteria of eligibility and regulatory and administrative formalities, whether set at a local, regional or national level, as it would impose if this healthcare were provided in its territory".

It should be noted that the provisions of the cross-border directive, in principle, apply to patients who decide to seek healthcare in a Member State other than the Member State of affiliation. In other words, if the patient for whom the country of insurance is Poland decides to use medical services in another EU Member State (Member State of treatment), then under the terms of the above-mentioned Directive and the laws of the Member States concerned, he or she will be able to claim reimbursement of cross-border healthcare. From the point of view of the issue under discussion, the key is that the reimbursement also includes the costs of "healthcare received through telemedicine".

Nevertheless, the practical recovery of costs incurred by the insured who has used cross-border healthcare with the use of telemedicine solutions can be quite difficult. In principle, a Member State is to reimburse the costs incurred by the insured person who benefits from cross-border healthcare if the healthcare in question falls within the range of benefits to which the insured person is entitled in the Member State of affiliation. This means, therefore, that both the treatment state and the Member State from which the insured person comes from should provide public funding for a particular benefit.

For example, in Poland, telemedical services financed from the resources of the National Health Fund are, *inter alia*, the cardioridical teleconsilium and geriatric teleconsilium, referred to in Regulation No. 127/2017/DSOZ of the President of the National Health Fund of 19 December 2017 on determining the conditions for the conclusion and implementation of

¹ COM (2015) 192 final.

² OJ L 88, 4.4.2011, pp. 45–65.

contracts such as health services separately contracted¹. In view of the above, a patient insured in another EU country would be able to demand reimbursement from the state of insurance if he or she took treatment in Poland including one of the above-mentioned services. Nevertheless, the real barriers to obtaining reimbursement for services classified as telemedicine are both their low availability in the public health service² and the lack of standardization at the level of individual Member States (Raposo, 2016). Therefore, patients may have in practice difficulty getting these benefits. However, even if they are implemented, there may be difficulties in obtaining reimbursement (e.g. due to the fact that for a given range of benefits a patient seeking a refund will not be entitled in the Member State of affiliation).

Therefore, it is not surprising that the refund system established by Directive 2011/24/EU does not have a real impact on EU citizens. As follows from the most recent report from the Commission on the application of patients' rights in cross-border healthcare, in all three years covered by the report (2015-2017), the total number of such claims for reimbursement was relatively small as part of the total patient care, and had stayed at a stable level³. Thus, in 2015, a total of 180 704 applications were positively examined in 19 Member States and Norway; in 2016, 209 568 applications were positively examined in 22 Member States; and in 2017, a total of 194 292 applications were positively considered in 20 Member States. Also in the financial dimension, the value of funds covered by the regulations of Directive 2011/24 / EU does not make a special impression. The expenditure across the EU on cross-border healthcare incurred under the Directive may therefore be estimated at 0.004% of the EU-wide annual healthcare budget. These are of course rough figures, but when read in conjunction with the figures of the cost of cross-border healthcare under the Regulations (which amounts to approximately 0.1%), it is clear that the vast majority of healthcare budgets is spent domestically. As the figures have been moderate and stable over the years, the impact on national health budgets arising from patients wishing to access cross-border healthcare appears marginal. This is true for all countries, no matter whether they introduced prior authorisation or not.

Transferring the above observations to the field of telemedicine considerations, it can be concluded that between 2015 and 2017, the reimbursement of costs incurred by insured persons who used cross-border healthcare received via telemedicine does not generally exist or constitutes a margin of the entire refinancing system. Importantly, the European Parliament reached similar conclusions. In Resolution of 12 February 2019 on the Implementation of the Cross-Border Healthcare Directive, the European Parliament pointed out that "application of the directive with regard to telemedicine – health services provided remotely – has led to a certain lack of clarity concerning reimbursement schemes, as some Member States do reimburse or provide consultation with general or specialised practitioners at a distance, while others do not"⁴. While the above-mentioned initiative should be evaluated

¹ Original title: Zarządzenie Nr 127/2017/DSOZ Prezesa Narodowego Funduszu Zdrowia z dnia 19 grudnia 2017 r. w sprawie określenia warunków zawierania i realizacji umów w rodzaju świadczenia zdrowotne kontraktowane odrębnie

² For example, according to the Informator of the Małopolska Branch of the National Health Fund, as of December 2017, only four medical doctors in the whole Małopolskie voivodeship offered Geriatric Teleconsultation. Data regarding Teleconsultation cardiology (4 sites) were not much better. It is worth noting, however, that all branches that contracted telemedicine services financed by the NFZ were located in Cracow. See: Informator of the Małopolska Agency of the National Health Fund titled: *Jak i gdzie się leczyć* [interactive]. [accessed: 09.05.2019]. <http://www.nfz-krakow.pl/download/gfx/nfz-krakow/pl/defaultstronaopisowa/344/3/1/nfz_krakow-jak_i_gdzie_sie_leczyc_luty2018.pdf>. http://www.nfz-krakow.pl/defaultstronaopisowa/344/3/1/nfz_krakow-jak_i_gdzie_sie_leczyc_luty2018.pdf (dostęp dnia: 01.02.2019).

³ COM (2018) 651 final.

⁴ 2018/2108(INI).

positively, previous experience confirms that similar activities have not yet brought the expected results. It seems, however, that patients who see the benefits of telemedicine solutions often do not wait for their implementation into public health services, but decide to cover the costs of teleconsultation or telecare on their own (TGR, 2018).

The impact of EU sectoral legislation on medical services utilizing telemedicine solutions

To make the picture complete, it must be noted that the considerations regarding the legal framework for the provision of medical services using telemedicine solutions also requires the inclusion of a number of EU sectoral legislation (Raposo, 2016). The basic act in this area is undoubtedly Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (so-called General Data Protection Regulation: GDPR)¹. An obvious issue is the fact that due to the use of various types of IT systems for the purpose of providing health services, sensitive data is processed and covered by special legal protection. It was provided, among others in Art. 9 GDPR, which introduces a general ban on processing, inter alia, personal health data. Because of that, any processing of personal data with regard to telemedicine solutions should be carried out in accordance with this Regulation, regardless of whether the processing itself takes place within the Union. For example, the abovementioned ban does not apply if a patient as the data subject has given explicit consent to the processing of those personal data for one or more specified purposes, except where the Union or Member State law provide that the prohibition referred to in Art. 9 para. 1 GDPR may not be lifted by the data subject.

The protection of personal data is not limited to the provisions of the GDPR and national regulations related to it. Due to the fact that ICT systems are particularly vulnerable to various types of attacks, measures have been taken for several years to increase the so-called cybersecurity. An expression of this trend is Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union². For example, in Poland, the provisions of this Directive are implemented by the Act of 5 July 2018 on the national cyber security system³. From the point of view of the aforementioned telemedicine, this means that entities operating in the health care sector, including healthcare entities, are counted among the group of operators of essential services. As a result, there are special obligations in the field of cyber security imposed on these entities, and therefore also on entities providing health services with the use of telemedicine solutions..

Admittedly, the freedom to provide services, although it is subject to certain limitations in the case of telemedicine (e.g. sensitive data), Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') still remains important for this kind of activities⁴. Other EU regulations relevant to telemedicine are undoubtedly the EU legislation relating to the protection of consumer rights.

¹ OJ L 119, 4.5.2016, pp. 1–88.

² OJ L 194, 19.7.2016, pp. 1–30.

³ Journal of Laws of 2018, item 1560, as amended. (Dz.U. z 2018 r. poz. 1560).

⁴ OJ L 178, 17.07.2000, pp. 1–16.

Finally, the newly issued Regulation 2017/745 on medical devices has repealed former provisions of Directive 93/42/EEC and provided a very detailed framework, including 123 articles and 17 technical annexes¹. Pursuant to recital 1 of abovementioned act, “this Regulation aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a high level of protection of health for patients and users, and taking into account the small- and medium-sized enterprises that are active in this sector”. As the Botrugno quite rightly points out “although the Regulation does not explicitly mention telemedicine or mHealth, it is worth remembering that the implantable devices are playing an increasing role in the development of remote care services, especially in the field of telemonitoring and mHealth” (Botrugno, 2018). Furthermore, the same Author states that “Regulation 2017/745 does contain provisions that might apply to telemedicine, especially where it states that devices intended with both a medical and a non-medical purpose must fulfil cumulatively the requirements applicable to both categories (...)” (Botrugno, 2018).

An attempt to comprehensively address the phenomenon of telemedicine from the point of view of EU law goes well beyond the scope of this study. Summing up this part of the considerations, it should be emphasized that the phenomenon of telemedicine is an extremely complex issue. It means, therefore, that an attempt to provide health services based on such solutions requires an extremely comprehensive approach, taking into account not only the normative material related to the health sector but also a number of sectoral regulations.

The EU Member States’ perspective

Under EU law, there are no regulations that would address the issue of telemedicine in a comprehensive manner. Although some of the provisions are subject to harmonization (e.g. protection of personal data, consumer rights), EU Member States have still the jurisdiction in telemedicine. One limitation of this research is that the studies were limited only to few UE countries. Despite this, it can be state that the minimum harmonisation of law in this area has caused legal fragmentation in the Member States regulations which regard telemedicine. As a result, the legal frameworks, approaches and levels of telemedicine development differ enormously among the Member States. Incidentally, it should be also pointed out that the telemedicine Market is very dynamic. Therefore, it is difficult to compare the present situation in the EU Member States. Admittedly, there are some studies which examine the telemedicine market in Europe, for example PWC report in 2018, but some data used in these studies come from research or surveys carried out in 2013. Of course, such reports should be assessed positively, although you may have doubts as to the extent of their the time they cover.

Studies on the regulation among the EU Member States also leave a lot to be desired. Even though there are available some general conclusions, nowadays it is difficult to find a summary guide of telehealth-related policies, laws, and regulations for all EU Member States. Therefore, the activity of the Center for Connected Health Policy in the United States of America may be an example of good practice for the EU institutions. Namely, the CCHP has produced a comprehensive 50 state survey of telehealth laws and Medicaid reimbursement policies which is utilized by key stakeholders including the Center for Medicare and Medicaid Services. The above-mentioned project was financed by the Department of Health and Human Services of the USA, in particular from the resources of the Office for the Advancement of

¹ OJ L 117, 5.05.2017, pp. 1–175.

Telehealth, Health Resources and Services Administration¹. Nowadays, the activity of the CCHP results in wide transparency on the telehealth (telemedicine) policy in the USA. For example, the CCHP publishes the current state laws and reimbursement policies, legislation and regulation tracking and additional reports.

In conclusion, it must be stressed that telemedicine legislation is not harmonized around the EU Member States. However, some of the EU Member States are aware of the limitations of their legal regulations in relation to the challenges of telemedicine. Hence, it should not come as a surprise that the countries initiate legislative activities aimed at creating convenient conditions for the implementation of telemedicine solutions. For example, such initiatives were taken in France. According to G. Lacroix, in France, "since September 15, 2018, healthcare professionals are entitled to conduct remote consultations at the same rate as face-to-face appointments. The reimbursement procedure by the Health Insurance Fund and supplemental healthcare insurance schemes are similar to the procedure currently applicable to standard appointments" (Lacroix, 2018). Another EU Member State that is trying to regulate this area is Switzerland (Pietro and Francetic, 2018).

Some remarks on Polish regulations on telemedicine

Poland is one of the EU Member States that recognises the advantages of telemedicine. It should be pointed out that the term "telemedicine" has been present in the Polish legal system since 2011 (Walczak and Polkowski). Nevertheless, the first attempt to regulate some aspects of telemedicine was the Act of 9 October 2015 amending the Act on the healthcare information system and certain other laws². The above-mentioned Act amended, *inter alia*, the Act of 15 April 2011 on medical activity³. It should be pointed out that before 12 December 2015, the provision of Art. 3 (1) of the Act on medical activity provided that "healing activities consist in providing health services"⁴. In relation to the aforementioned amendment, the cited provision was supplemented with the information indicating that "these services may be provided via information and communication technologies systems or communication systems". Although the legislator did not use expressly the term telemedicine, it is beyond discussion that the new provisions aimed to create a legal framework for the development of telemedicine solutions in healing activities. What is more, there were a few significant amendments in the Act of 5 December 1996 on the professions of a physician and dentist⁵.

As a result, from 12 December 2015, we can talk about a kind of "legalization" of telemedicine solutions in Poland. Nevertheless, the process of adopting legal solutions enabling a wider use of information and communication technologies in the area of health protection is still in progress. This is demonstrated by further interventions of the legislator in this area, such as the Act of 1 March 2018 on amending certain acts in connection with the introduction of an e-prescription⁶ or the Act of 20 July 2018 amending the Act on the

¹ Grant #G22RH30365. See: <https://www.hrsa.gov/sites/default/files/hrsa/ruralhealth/resources/telehealth/oat-grantees-2017-profiles.pdf>.

² Journal of Laws of 2015, item 1991. *Original title*: Ustawa z dnia 9 października 2015 r. o zmianie ustawy o systemie informacji w ochronie zdrowia oraz niektórych innych ustaw.

³ Journal of Laws of 2018, item 2190 as amended. *Original title*: ustawa z dnia 15 kwietnia 2011 r. o działalności leczniczej.

⁴ Brzmienie oryginalne: Działalność lecznicza polega na udzielaniu świadczeń zdrowotnych.

⁵ Act of 5 December 1996, the professions of a physician and dentist. Journal of Laws of 2019, item 537 as amended. *Original title*: ustawa z dnia 5 grudnia 1996 r. o zawodach lekarza i lekarza dentystry.

⁶ Journal of Laws of 2018, item 697. *Original title*: ustawa z dnia 1 marca 2018 r. o zmianie niektórych ustaw w związku z wprowadzeniem e-recepty.

information system in protection of health and some other laws¹. Finally, the very recent regulation on telemedicine in Poland is the Regulation of the Minister of Health of 11 April 2019 on the organizational standards of healthcare in the field of radiology and imaging diagnostics performed via IT systems². There is no doubt that the last Act of law should be crucial in the physicians' practice. For example, the above-mentioned Regulation specifies the conditions for the implementation of teleradiology services. In addition, the regulation clearly states that "a teleradiology service is not performed if the method of radiological examination, the radiological image quality or clinical data sent by the contracting authority are not sufficient to assess the radiological image". It can therefore be concluded that the indicated regulations constitute one of the first attempts to standardize the way of performing one of the types of telemedicine in Poland (teleradiology).

While the legislator tries to respond to the demand of the practice, still the entities interested in the development of telemedicine (starting from entities conducting medical activities, through people performing medical professions, and ending with patients) report numerous objections to the current regulations. As a result, there are still legal doubts about the activities which healthcare professionals may conduct using the telemedicine solutions. Probably, it is one of the biggest barriers to the development of telemedicine in Poland. Therefore, the telehealth market revenue per inhabitant in euros is in Poland one of the lowest among the EU Member States (1.62 Euro per inhabitant)³. In comparison, in Denmark it is above 6 Euro, in Sweden above 5 Euro and in Netherlands, Germany, Austria, Finland and France above 4 Euro. Another reason for such a situation concerning the telehealth market revenue may be lack of an overall strategy for telemedicine in Poland. There is also lack of awareness among the patients about such solutions (LekSeek and GABINETdrWidget²⁰¹⁸). On the other hand, the competition on the Polish telemedicine market is still not impressive.

To sum up, the Act of 9 October 2015 amending the Act on the healthcare information system and certain other laws did not contribute to the dynamic development of telemedicine services in Poland. As a result, access to health services provided in a telemedicine manner is still quite limited. It seems, therefore, that the current regulations in the field of telemedicine solutions require further revision to adapt to the real needs of patients as well as healthcare providers.

Conclusions

As stated in the Introduction, the main goal was to analyse and evaluate EU policies and legislation concerning telemedicine. In the light of the research conducted, it must be stressed that the European Union is consistently trying to promote telemedicine solutions in healthcare systems around the EU Member States. The evidence for this is quite an important place of telemedicine in the EU health and digital policies. On the other hand, most regulations concerning directly telemedicine occur in the area of *soft law*. As a result, the EU Member States have still jurisdiction in telemedicine. Because of that, the legal frameworks,

¹ Journal of Laws of 2018, item 1515 as amended. *Original title*: ustawa z dnia 20 lipca 2018 r. o zmianie ustawy o systemie informacji w ochronie zdrowia oraz niektórych innych ustaw.

² Regulation of the Minister of Health of 11 April 2019 on the organizational standards of healthcare in the field of radiology and imaging diagnostics performed via teleinformatic systems. Journal of Laws of 2019, item 834 as amended. *Original title*: rozporządzenie Ministra Zdrowia z dnia 11 kwietnia 2019 r. w sprawie standardów organizacyjnych opieki zdrowotnej w dziedzinie radiologii i diagnostyki obrazowej wykonywanej za pośrednictwem systemów teleinformatycznych.

³ The telemedicine market revenue per inhabitant is lower only in Hungary (1.25 Euro), Bulgaria (1.11 Euro) and Romania (1.04 Euro).

approaches and levels of telemedicine development differ enormously among the Member States.

It should be also noted that the provisions of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare guarantee the reimbursement of "healthcare received through telemedicine". Nevertheless, the application of Directive 2011/24/EU has led to a certain lack of clarity concerning reimbursement schemes, as some Member States do reimburse or provide consultation with general or specialised practitioners at a distance, while others do not. What is more, in some countries there is still low availability of telemedicine solutions financed by public health service systems. Therefore, patients may have difficulty getting these benefits. However, even if there are implemented, there may be difficulties in obtaining reimbursement (e.g. due to the fact that for a given range of benefits a patient seeking a refund will not be entitled in the Member State of affiliation).

Returning to the question posed at the beginning of this study, it is now possible to state that the phenomenon of telemedicine is an extremely complex issue. This implies that the attempt to provide health services based on such solutions requires a comprehensive approach, taking into account not only the normative material related to healthcare but also a number of sectoral regulations relating to, for example, personal data protection and cybersecurity rules, regulations on medical devices, patient rights, or to the provisions governing electronic commerce. Such a level of complexity may be a huge barrier for entrepreneurs, especially for young start-ups which try to implement new services on the EU market. This has led authors such as for instance Botrugno to conclusion that there is a need for an adequate regulatory framework to address the challenges posed by telemedicine in routine healthcare. On the other hand Raposo states that the EU can only aspire to create a legal framework for those domains in which European law had already had any kind of inventions and adapt it to the specificities of telemedicine.

In the discussion about telemedicine there are also some fears, which may affect the future regulations in this area. For example, in the European Economic and Social Committee opinion, adopted at the plenary on 19 September 2018, it was stressed that "in the course of the changes generated by digital transformation, people must be at the centre of care". In this context, the European Economic and Social Committee pointed out that "the rapid expansion of telemedicine, connected devices and nanotechnology, biotechnology, information technology and the cognitive sciences (NBIC) must not result in patients being seen as mere connected bodies which can be analysed, monitored and overseen remotely by an all-powerful IT programme". As a result, the technical development of health in fact encourages - in the European Economic and Social Committee's opinion - the opposite: it places interpersonal relationships and social ties back at the centre of medical practice and care.

Therefore, bearing in mind both, the benefits of telemedicine and the threats resulting from it, a fundamental question arises: how to ensure the development of telemedicine in the EU, which will also properly protect the welfare of patients. The findings of this study indicate that it is necessary to enact a uniform strategy for the development of telemedicine. For that purpose, the precise legal definition of telemedicine should be proposed. Secondly, the institutions involved in the EU legislation should focus on implementing general standards in different areas of telemedicine (e.g. technology, data protection, professionals behaviours etc.). It is no doubt that such standards should increase patients' welfare. Although such standards and guidelines exist but they are usually passed by medical boards or informal associations, which means that these documents are not legally binding regulations.

In this context, the EU institutions should consider a certification system for entities or for technologies which classify as telemedicine solutions. There should be also precise

regulations which solve the problem of responsibility in case of malpractice or an accident. Another type of guarantees for patients, as well as for physicians and other medical professionals, may be an obligatory insurance for the entities and professionals that provide such services. Finally, the significant challenge is to provide interoperability between telemedicine solutions available around the European Union. This is a *sine qua non* condition for cross-border utilization of telemedicine solutions by EU citizens.

This work has proved that there should be a wide, interdisciplinary discussion around the EU. It should be pointed out that regulating such a complex area is a huge challenge. On the one hand, over-regulation could place unnecessary restrictions on the telemedicine development. On the other, legal instruments may promote and stimulate the implementation of telemedicine solutions. Because of that, it is so important to find adequate regulations in this area. Consequently, the proposed area of research may be very attractive for scientist in the field of public economic law.

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